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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ricardo Blank

8496-US

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74476

7590

06/03/2009

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EXAMINER

MARCETICH, ADAM M

ART UNIT

PAPER NUMBER

3761

NOTIFICATION DATE

DELIVERY MODE

06/03/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

athena.pretory@us.nestle.com  
patentdepartment@rd.nestle.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/701,698	<b>Applicant(s)</b> BLANK ET AL.	
	<b>Examiner</b> Adam Marcetich	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,3,7,8 and 10-36 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3,7,8,10-24 and 27-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 November 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. 0226730.0, filed on 18 November 2002 in the United Kingdom has been filed. Therefore, a priority date of 18 November 2002 is given to claims 2,3,7,8 and 10-36.

### ***35 USC § 112, 6<sup>th</sup> Paragraph***

2. Regarding Applicant's:

“first means for threadably attaching” of claims 2, 20, 21, 24 and 29,

“second means for opening” of claims 2 and 3,

“third means for fixedly attaching” of claim 2,

“attachment means for fixedly attaching” of claims 7, 8, 27 and 28,

“first venting means for venting” of claims 10 and 11,

“second venting means” of claim 12,

“dosing means for controlling” of claim 16,

“first rim means” of claims 30, 31 and 33,

“second rim means” of claims 30, 32 and 34-36,

3. the language appears to be an attempt to invoke 35 USC 112, 6<sup>th</sup> paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 USC 112, 6<sup>th</sup> paragraph if it meets the following 3-prong analysis:

(A) The claim limitations must use the phrase “means for” or “step for;”

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(B) the “means for” or “step for” must be modified by functional language;  
and

(C) the phrase “means for” or “step for” must not be modified by sufficient structure, material or acts for achieving the specified function.

If the examiner finds that a prior art element:

(A) performs the function specified in the claim,

(B) is not excluded by any explicit definition provided in the specification for an equivalent, and

(C) is an equivalent of the means- (or step-) plus-function limitation,

then the prior art element may be considered by the examiner to be an equivalent to the means plus function limitation, and the prior art may anticipate the claimed limitation. See MPEP 2183.

4. Regarding claims 2, 3, 7, 10, 11 and 16, Applicant appears to have met the requirements set forth in MPEP §2181, and Examiner has turned to the specification for clarification.

5. Regarding claims 8, 12, 20, 21, 24 and 27-36, Applicant appears to not meet the requirements set forth in MPEP §2181, because the claims contain sufficient structure, material or acts for achieving the specified function.

***Claim Rejections – 35 USC § 103***

6. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

9. Claims 2,3,7,8,17,19,24,27,28 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, Susumu et al. (US 20040104246) in view of Rule; Arthur W. T. (US 4801007).

10. Regarding claims 2 and 7, Kawaguchi discloses a connector device for connecting a feeding line of an enteral administration set to a laminated paper packaging system containing a composition (¶ [0027], Figs. 1, 5, adapter body 12 / 112 connecting to pack 20), the connector device comprising:

a rigid tube part being adapted to sealingly attach to the feeding line of the enteral administration set (¶ [0038], Fig. 5, annular ridges JR connecting to tube 30);

the tube part defining a first part of a passageway allowing the flow of the composition contained in the laminated paper packaging system to the feeding line of the enteral administration set (¶ [0057], Fig. 5, upper part of passage 112g connecting to tube 30);

first means for threadably attaching the rigid tube part to the laminated paper packaging system, whereby the connector is screwed to the laminated paper packaging system (¶ [0049], Fig. 5, annular member 112b threadably attaching adapter body 112 to linking member 114 on pack 20);

the first means further defining a second part of the passageway when threadably attached to the laminated paper packaging system (Fig. 5, lower part of passage 112g below annular rim 112b); and

second means for opening the laminated paper packaging system upon screwing the connector device onto the laminated paper packaging system (¶ [0049], [0051], Fig. 5, pointed end 112a).

Kawaguchi discloses the invention substantially as claimed, see above.

However, Kawaguchi lacks third means for fixedly attaching as claimed [claim 2]. Rule

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discloses a teat unit for connection with laminated paper containers (col. 1, lines 8-18, 33-40, col. 3, lines 11-16, 40-42, Figs. 1, 3, teat unit 21 for connecting to container 11) comprising:

a third means for fixedly attaching a rigid tube part to a laminated paper packaging system (col. 4, lines 12-23, Figs. 6, 7, mounting 31 comprising flange 35 with shoulder 36);

whereby the connector device is secured to an interior surface within the laminated paper packaging system (col. 4, lines 24-31, container wall 15 snapping between seal 37 and flange 35).

Rule securely seals a rigid tube to the interior of a laminated container, to prevent the tube from dislodging during use. One would be motivated to modify Kawaguchi with the third means for fixedly attaching as taught by Rule to secure a rigid tube, since each of the immediate invention, Kawaguchi and Rule place a rigid tube through an opening in a laminated container.

11. Regarding claims 13 and 19, Kawaguchi discloses a prefabricated enteral administration system comprising

an enteral administration set (¶ [0027], [0032], Figs. 1, 5, tube 30); and

a connector device non-releasably connected to the enteral administration set (¶ [0032], Figs. 1, 5, adapter body 112 connecting to tube 30).

Examiner interprets the connection between tube 30 and ridges JR as a “non-releasable” attachment, since a specific amount of force is required to separate the components (¶ [0038]). That is, tube 30 and ridges JR will not detach during normal use

unless a user pulls the tubes forcefully. Kawaguchi discloses the invention as substantially claimed; see above. However, Kawaguchi lacks a third means for fixedly attaching as claimed [claims 2, 13 and 19]. See discussion of claims 2 and 7 above regarding rationale and motivation to modify Kawaguchi in view of Rule.

12. Regarding claim 17, Kawaguchi discloses an enteral administration kit comprising:

an enteral administration set (§ [0027], [0032], Figs. 1, 5, tube 30); and  
a laminated paper packaging system containing a composition to be enterally administered to a patient (§ [0028], [0049], Fig. 5, pack 20). Examiner cites Rule to remedy the deficiencies of Kawaguchi. See discussion of claim 2 above regarding rationale and motivation to modify Kawaguchi in view of Rule.

13. Regarding claim 27, Kawaguchi discloses the invention as substantially claimed, including an adhesive layer (§ [0058], Fig. 5, adhesive layer 114c). However, layer 114c of Kawaguchi engages the first surface of a package before a spike penetrates the package. Therefore, Kawaguchi lacks an adhesive layer having the claimed function [claim 27]. Rule discloses an attachment means comprising a sealing member that engages the first surface of the laminated paper packaging system subsequent to penetration of the first spike (col. 4, lines 24-31, Fig. 7, seal 37). One would be motivated to modify Kawaguchi in view of Rule by including an adhesive layer as taught by Kawaguchi in the seal 37 of Rule to attach a connecting member to a package, since the adhesive layer performs the same function of securing a connector member to a



package in both cases. That is, Rule calls for secure sealing between a connecting member and package by including seal 37 in the connecting member.

14. Regarding claim 28, Kawaguchi discloses the invention as substantially claimed, including adhesive layer 114c; see above. However, Kawaguchi lacks a first annular rim as claimed [claim 28]. Rule discloses a first annular rim (col. 4, lines 12-23, Figs. 6, 7, flange 33). See discussion of claim 27 above regarding rationale and motivation to apply an adhesive layer as taught by Kawaguchi to the seal 37 of Rule.

15. Regarding claim 8, Kawaguchi discloses a connector device wherein the first spike defines a point (¶ [0049], [0051], Fig. 5, pointed end 112a). Kawaguchi discloses the invention as substantially claimed; see above. Examiner cites Rule as teaching a first rim; see discussion of claim 28 above. Rule discloses an attachment means further comprising a second rim on the spike formed of a flexible material and located a second distance from the point of the spike, the second distance being less than the first distance (col. 4, lines 12-23, Figs. 6, 7, flange 35). Rule discloses first and second rims as discussed above. Regarding the limitations of “rigid” and “flexible” materials, Applicant has not defined these terms in the specification; therefore Examiner interprets the plastic material forming flanges 33 and 35 of Rule as being rigid and flexible. That is, plastics are routinely formulated to have both rigid qualities. In this case, the plastic of Rule is interpreted as having a rigid quality (to pierce a laminated container and engage a teat unit 21) and a flexible quality (Rule col. 5, lines 39-43, polythene known as flexible plastic).

16. Regarding claim 24, Kawaguchi discloses a connector device wherein:

the laminated paper packaging system includes a first surface with a frame-like member defining an annular threaded projection (§ [0049], [0050], Fig. 5, linking member 114 attached to pack 20, defining cylindrical component 114a with male threads 14s); and

wherein the first means comprises a threaded annular portion complementary to the threaded projection of the laminated paper packaging system (§ [0050], Fig. 5, annular member 112b threading to cylindrical component 114a).

17. Regarding claim 3, Kawaguchi discloses a second means comprising a cutting member protruding from the connector device in a direction towards the laminated paper packaging system for cutting the laminated paper packaging system upon screwing the connector device onto the laminated paper packaging system (§ [0049], [0051], Fig. 5, pointed end 112a).

18. Regarding claims 30 and 33-36, Kawaguchi discloses a connector device substantially as claimed including a rigid tube part; see above. However, Kawaguchi lacks first and second rim means as claimed [claim 30]. Rule discloses:

[30, 33] a rigid tube part having at about said second end a first rim means that is a flange (col. 4, lines 12-23, Figs. 6, 7, flange 33 and seal 37); and

[30, 34, 36] a second rim means that is a flange or thickened portion, more distal thereon (col. 4, lines 12-23, Figs. 6, 7, flange 35);

[30, 33] wherein, upon engagement of said connector device to said top portion of said package, said first rim means engages the outer surface of said top portion of said package (Figs. 6, 7, flange 33 and seal 37 engaging laminate 15);

[30, 34, 35, 36] said second rim means engages a corresponding inner surface of said top portion of said package, sealingly attaching said connector device to said package between said first and second rim means (col. 4, lines 24-31, Fig. 7, flange 35 engaging inner surface of laminate 15);

[35] said second rim means is a recess portion on said rigid tube part (Figs. 6, 7, shoulder 36 of flange 35 forming recess);

[35] said connector device sealingly engaging the inner surface of said top portion of said packaging along said recess portion upon engagement of said connector device to said package.

See discussion of claims 2 and 7 above regarding rationale and motivation to modify Kawaguchi in view of Rule.

19. Regarding claims 31 and 32. Kawaguchi discloses the invention as substantially claimed; see above. However, Kawaguchi lacks first and second rim means as claimed [claims 31 and 32]. Rule discloses first and second rims as discussed for claim 30 above. Regarding the limitations of “rigid” and “flexible” materials, Applicant has not defined these terms in the specification; therefore Examiner interprets the plastic material forming flanges 33 and 35 of Rule as being rigid and flexible. That is, plastics are routinely formulated to have both rigid qualities. In this case, the plastic of Rule is interpreted as having a rigid quality (to pierce a laminated container and engage a teat

unit 21) and a flexible quality (Rule col. 5, lines 39-43, polythene known as flexible plastic).

20. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, Susumu et al. (US 20040104246) in view of Rule; Arthur W. T. (US 4801007), further in view of Evans; Robert P. (US 2668533).

21. Regarding claims 10 and 11, Kawaguchi in view of Rule discloses the invention substantially as claimed, see above. However, Kawaguchi in view of Rule lacks venting means as claimed [claims 10 and 11]. Evans discloses a medical liquid dispenser (col. 1, lines 1-5, 30-42, Fig. 1, outlet member 18) comprising:

a first venting means for venting an interior of a liquid container comprising a valve, which allows air to enter through the valve means while preventing a composition to be administered to exit (col. 2, lines 45-52, col. 3, lines 47-59, Fig. 2, ball check valve member 56). Evans balances the volumes of dispensed fluid with an equal volume of air. One would be motivated to modify Kawaguchi in view of Rule with the venting means as taught by Evans to restore volume to a laminated package since a partial vacuum will prevent fluid from passing to a patient. That is, if air is not returned to a supply container, the fluid will not flow through effectively. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kawaguchi in view of Rule as discussed with the venting means as taught by Evans in order to dispense fluid effectively and prevent a vacuum.

22. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, Susumu et al. (US 20040104246) in view of Rule; Arthur W. T. (US 4801007) in view of Evans; Robert P. (US 2668533), further in view of Quinn; David G. et al. (US 4921138).

23. Regarding claim 12, Kawaguchi, Rule and Evans disclose the invention substantially as claimed, see above. However, Kawaguchi, Rule and Evans lack a visualization tube and second venting means as claimed [claim 12]. Quinn discloses an enteral fluid dispenser (col. 2, lines 51-55, col. 5, lines 25-34, Fig. 1, fluid dispensing device 24) for connection to a laminated paper package (col. 1, lines 35-39), further comprising:

a visualization tube (col. 5, lines 25-34, Fig. 1, column 26);

one end of the visualization tube being connected to a passageway for the composition to be administered (col. 5, lines 50-55, Fig. 3, spike 58 connecting to lowermost corner 18); and

the other end of the visualization tube being connected to a second venting means (col. 5, lines 25-34, Figs. 1, 3, venting port 32);

the second venting means comprising an air inlet and a second spike adapted to penetrate a second surface of the laminated paper packaging system corresponding to a predetermined fluid level of the composition (col. 5, lines 25-34, 50-55, Figs. 1, 3, venting port 32 in fluid communication with spike 56). Evans displays the remaining level of nutrient solution (cols. 6-7, lines 64-2) while preventing a vacuum from forming

inside a supply package (col. 5, lines 25-34). One would be motivated to modify Kawaguchi, Rule and Evans with the visualization tube and second venting means as taught by Quinn to display a level of nutrient solution since This prevents solution from being wasted. Kawaguchi calls for conserving nutrient solution by dispensing all remaining fluid (§ [0054], Fig. 7, discharge hole DH dispensing all fluid from container). Showing whether fluid remains in a supply package prevents it from being wasted. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kawaguchi, Rule and Evans as discussed with the visualization tube and second venting means as taught by Quinn in order to prevent both a vacuum and wasted solution.

24. Claims 13, 14, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, Susumu et al. (US 20040104246) in view of Rule; Arthur W. T. (US 4801007), further in view of Schafer (US 5993422).

25. Regarding claims 13, 14 and 16, Kawaguchi in view of Rule discloses the invention substantially as claimed, see above. However, Kawaguchi in view of Rule lacks a pump unit or dosing means as claimed [claims 13 and 16]. Schafer discloses a device for dosing enteral fluids (col. 1, lines 44-47) from a laminated container (col. 4, lines 41-46, Fig. 5, container 29), comprising a pump unit arranged in the feeding line of the enteral administration set. (col. 3, lines 54-59, Fig. 1, pump unit 2). Schafer delivers nutrients at variable rates, independent of the viscosity of a nutrient solution (col. 2, lines 12-16 col. 3, lines 10-16). Additionally, Schafer delivers these nutrients

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independent of the level of nutrient solution remaining in a container. One would be motivated to modify Kawaguchi in view of Rule with the dosing means as taught by Schafer to deliver solution accurately since a viscous solution may require additional force to dispense it to a patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kawaguchi in view of Rule as discussed with the dosing as taught by Schafer in order to dispense viscous solutions at a precise rate.

26. Regarding claim 18, Kawaguchi discloses an enteral administration kit comprising:

an enteral administration set (§ [0027], [0032], Figs. 1, 5, tube 30); and  
a laminated paper packaging system containing a composition to be enterally administered to a patient (§ [0028], [0049], Fig. 5, pack 20). Examiner cites Rule to remedy the deficiencies of Kawaguchi. See discussion of claim 2 above regarding rationale and motivation to modify Kawaguchi in view of Rule.

27. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, Susumu et al. (US 20040104246) in view of Rule; Arthur W. T. (US 4801007) in view of Schafer (US 5993422), further in view of Broman; Cyrus R. (US 2969063).

28. Regarding claim 15, Kawaguchi, Rule and Schafer disclose the invention substantially as claimed, see above. However, Kawaguchi, Rule and Schafer lack an intermediate bag as claimed [claim 15]. Broman discloses a parenteral fluid set (col. 1,

lines 15-19, 63-70, Fig. 1, administration set) comprising a transparent intermediate bag (col. 2, lines 19-26, Fig. 1, device 22 made of translucent PVC). Broman accurately delivers discrete amounts of fluid to a patient by clamping portions of an intermediate bag (cols. 3-4, lines 73-6, 27-29). One would be motivated to modify Kawaguchi, Rule and Schafer with the intermediate bag as taught by Broman to accurately dispense small volumes since a supply package may contain more solution than a patient will consume at a single meal. Additionally, Broman allows a caregiver to record the volumes of solution that a patient consumes. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kawaguchi, Rule and Schafer as discussed with the intermediate bag as taught by Broman in order to dispense fractional amounts of a supply container and accurately record the volumes a patient consumes.

29. Claims 20-23 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, Susumu et al. (US 20040104246) in view of Rule; Arthur W. T. (US 4801007) further in view of Ninomiya; Satoru et al. (US 5141133).

30. Regarding claim 20, Kawaguchi in view of Rule discloses the invention substantially as claimed, see above. including a rigid tube part, first means for threadably attaching, first and second parts of a passageway and a cutting member. See above. However, Kawaguchi in view of Rule lacks a cutting member that first cuts the surface only after engagement of the first means of the connector device with a first



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threaded portion of a packaging system as claimed [claim 20]. In other words, pointed end 112a of Kawaguchi cuts a surface before engagement of a first means.

Ninomiya discloses a pouring plug for piercing a laminated beverage pack (col. 3, lines 28-31, col. 4, lines 13-19, pouring plug for mounting to container wall 18).

Ninomiya demonstrates a cutting member that first cuts the surface only after engagement of the first means of the connector device with a first threaded portion of a packaging system (col. 4, lines 6-12, Fig. 3, tubular blade 12 not projecting from lower opening of tubular body 1 after mounting to threaded mounting portion 10). Here, Ninomiya prevents premature rupture of a sealed container (col. 6, lines 44-49, especially lines 56-59). In this rejection, Examiner shortens the lower portion of adapter body 112 of Kawaguchi to allow pointed end 112a to pierce pack 20 only after annular member 112b engages linking member 114. Alternatively, Examiner lengthens cylindrical component 114a for the same purpose. One would be motivated to modify Kawaguchi in view of Rule with the dimensions of a cutting member as taught by Ninomiya to prevent premature rupture that would create a leak.

31. Regarding claim 21, Kawaguchi discloses a cutting member integrally formed with the first means (Fig. 6, pointed end 112a formed integrally as part of adapter body 112).

32. Regarding claims 22 and 23, Kawaguchi discloses a prefabricated enteral administration system comprising:

[22] an enteral administration set and a connector device non-releasably connected to the enteral administration set (§ [0032], Figs. 1, 5, adapter body 112 connecting to tube 30); and

[23] a laminated paper packaging system containing a composition to be enterally administered to a patient (§ [0028], [0049], Fig. 5, pack 20).

Kawaguchi discloses the invention substantially as claimed, see above.

Examiner cites Rule to remedy the deficiencies of Kawaguchi, namely a first means that also fixedly attaches the rigid tube part to an interior surface of the laminated paper packaging of claim 20.

33. Regarding claim 29, Kawaguchi discloses a connector device wherein:

the first means includes a second threaded portion defined on the connector device (§ [0049], [0050], Fig. 5, cylindrical component 114a having male threads 14s); and

the second threaded portion being complementary to the first threaded portion of the frame-like member of the laminated paper packaging system such that the connector device threadably engages the frame-like member of the laminated paper packaging system (§ [0050], Fig. 5, annular member 112b threading to cylindrical component 114a).

***Response to Amendments***

34. Objection to claims 28 and 35 are withdrawn in view of the amendments filed 29 October 2008.

***Response to Arguments***

35. Applicant's arguments, see p. 9-12 filed 29 October 2008 with respect to the rejection(s) of claim(s) 2-3, 7-8, 10-24 and 27-36 under 35 USC § 103 over Kawaguchi '246 and Tallman '662 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 USC § 103 over Kawaguchi '246, Rule '007, Ninomiya '133, Schafer '422, Broman '063, Evans '533 and Quinn '138.

36. Applicant notes that the specification describes many related embodiments and sets forth aspects of those embodiments in the numerous interrelated illustrations, particularly, the connector device by the Roman numeral 1 throughout the descriptions of Figure 1-5, as well as the embodiments set forth in remaining Figures 6-9. Examiner has withdrawn the § 112, first paragraph, rejection of claims 2,3,8,10-18,20-24 and 27-29.

37. Applicant asserts that Tallman fails to remedy the deficiencies of Kawaguchi, namely attachment means fixedly attaching the connector device to an interior surface within the paper packaging system. Applicant reasons that Tallman spout 10 appears to operate by screwing the spout into place, and would be too destructive to cooperate

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with the more delicate packages in Kawaguchi. Examiner instead cites Rule '007 as teaching attachment means in the new grounds of rejection.

38. Applicant submits that the terms "rigid" and "flexible" used in claims 31, 32 and 34 are understood by one of skill in the art. However, Examiner notes that the terms are not given special meaning in the specification; therefore Examiner interprets the material of Rule as having both "rigid" and "flexible" qualities.

39. Applicant contends that Hegi fails to remedy the deficiencies of Kawaguchi, namely first and second rim means. Examiner instead cites Rule as teaching first and second rim means in the new grounds of rejection.

### ***Conclusion***

40. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

◆ Xuan; Jialuo US 5052614

41. Examiner has applied new grounds of rejection not necessitated by amendment. Therefore, the finality of the previous Office Action applied 06 June 2008 is withdrawn.

42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

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43. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

44. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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29 May 2009